

PATENT COOPERATION TREATY

11585546

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 16 JUN 2005

WIPO

PCT

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43b/s.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2005/000206

International filing date (day/month/year)
12.01.2005

Priority date (day/month/year)
15.01.2004

International Patent Classification (IPC) or both national classification and IPC
A61K35/78, A61P3/04

Applicant
MULTIPHARMA / GÖTEBORG AB

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b/s(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - Gitschiner Str. 103
D-10958 Berlin
Tel. +49 30 25901 - 0
Fax: +49 30 25901 - 840

Authorized Officer

Mateo Rosell, A.M.

Telephone No. +49 30 25901-319



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2005/000206

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2005/000206

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire International application,
☒ claims Nos. 1-16 with respect to industrial applicability

because:

- ☒ the said international application, or the said claims Nos. 1-16 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2005/000206

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-16
	No: Claims	
Inventive step (IS)	Yes: Claims	1-16
	No: Claims	
Industrial applicability (IA)	Yes: Claims	-
	No: Claims	

2. Citations and explanations
see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 1-16 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: Dullooo et al., 1999.Am.J.Clin.Nutr., 70: 1040-1045.

Novelty

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1 and shows that (see abstract and page 1041, left-hand column, 3rd paragraph to right-hand column, 1st paragraph; page 1042, right-hand column, last paragraph to page 1044, right-hand column, last paragraph) the references in parentheses applying to this document) the administration of a green tea extract, AR25 in form of capsules (containing 50 mg caffeine and 90 mg epigallocatechin gallate), promotes a significant increase in fat oxidation as compared to subjects taking caffeine alone (50 mg caffeine) or placebo.

The subject-matter of claims 1 and 9 differ from this known D1 in that the formulation of the present application incorporates diterpene forskolin, caffeoylquinic acids and flavonoids to the caffeine and catechines.

The subject-matter of claims 1 and 9 is therefore new (Article 33(2) PCT).

Inventive step

The problem to be solved by the present invention may be regarded as the provision of a pharmaceutical composition to treat obesity and associated metabolic syndrome.

The solution to this problem proposed in claims 1 and 9 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The combination of different extracts obtained from green tea (catechins such as epigallocatechin galate (EGCG)), Coleus forskholii (diterpene forskolin), yerba mate (caffeine and caffeoylquinic acids (cGA)) and Betula alba (flavonoids) act in concert, i.e. synergistically strengthening the two main effects of the mixture, i.e. the thermogenic effect (increased metabolic rate) and the decrease of the absorption of fat (see examples 3-5).

Claims 2-8 and 10-16 are dependent on claims 1 and 9 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Industrial applicability

For the assessment of the present claims 1-16 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

CORRECTED VERSION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43b/s.1)Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)Applicant's or agent's file reference
see form PCT/ISA/220**FOR FURTHER ACTION**
See paragraph 2 belowInternational application No.
PCT/EP2005/000206International filing date (day/month/year)
12.01.2005Priority date (day/month/year)
15.01.2004International Patent Classification (IPC) or both national classification and IPC
A61K35/78, A61P3/04Applicant
MULTIPHARMA / GÖTEBORG AB

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - Gitschiner Str. 103
D-10968 Berlin
Tel. +49 30 25901 - 0
Fax: +49 30 25901 - 840

Authorized Officer

Mateo Rosell, A.M.

Telephone No. +49 30 25901-319



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2005/000206**Box No. I Basis of the opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed,
 - ☐ filed together with the international application in computer readable form,
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2005/000206**Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Yes: Claims	1-16
	No: Claims	
Inventive step (IS)	Yes: Claims	1-16
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-16
	No: Claims	

2. Citations and explanations**see separate sheet**

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2005/000206**Re Item V****Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following document:

D1: Dulloo et al., 1999.Am.J.Clin.Nutr., 70: 1040-1045.

Novelty

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1 and shows that (see abstract and page 1041, left-hand column, 3rd paragraph to right-hand column, 1st paragraph; page 1042, right-hand column, last paragraph to page 1044, right-hand column, last paragraph) the references in parentheses applying to this document) the administration of a green tea extract, AR25 in form of capsules (containing 50 mg caffeine and 90 mg epigallocatechin gallate), promotes a significant increase in fat oxidation as compared to subjects taking caffeine alone (50 mg caffeine) or placebo.

The subject-matter of claims 1 and 9 differ from this known D1 in that the formulation of the present application incorporates diterpene forskolin, caffeoylquinic acids and flavonoids to the caffeine and catechines.

The subject-matter of claims 1 and 9 is therefore new (Article 33(2) PCT).

Inventive step

The problem to be solved by the present invention may be regarded as the provision of a pharmaceutical composition to treat obesity and associated metabolic syndrome.

The solution to this problem proposed in claims 1 and 9 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2005/000206

The combination of different extracts obtained from green tea (catechins such as epigallocatechin galate (EGCG)), Coleus forskholii (diterpene forskolin), yerba mate (caffeine and caffeoylquinic acids (cGA)) and Betula alba (flavonoids) act in concert, i.e. synergistically strengthening the two main effects of the mixture, i.e. the thermogenic effect (increased metabolic rate) and the decrease of the absorption of fat (see examples 3-5).

Claims 2-8 and 10-16 are dependent on claims 1 and 9 and as such also meet the requirements of the PCT with respect to novelty and inventive step.